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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,367

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Paul V. Goode JR.

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/633,367	<b>Applicant(s)</b> GOODE ET AL.	
	<b>Examiner</b> ROBERT L. NASSER	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 85-105 and 175-199 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-92, 94-105, 178-181, 185-188 and 192-199 is/are rejected.
- 7) ☒ Claim(s) 93, 175-177, 182-184 and 189-191 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/9/2004, 12/20/2004, 5/27/2005, 9/27/2007</u> .             | 6) <input type="checkbox"/> Other: _____                          |



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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

<sup>3</sup>

Claims 85-89, 91, 94, 96, 97, 99, 101-104, 178, 185, 192, 196-197, and 199 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin et al 2002/0161288. Shin teaches a continuous glucose monitor including a module to receive sensor data, a module to receive reference data from a reference sensor, a module to form matched pairs (see paragraph [0006]), and a module that evaluates the stability of the sensor(see paragraph [0050], particularly the last sentence). Claim 86 is rejected in that it is the examiner's position that since Shin uses sensor data to evaluate stability, it at least uses amplitude. Claim 87 is rejected in that Shin teaches that it waits until transients have diminished, i.e. the sensor is stable, before calibrating the sensor. It seems to the examiner that prior to calibration, there is no output. Hence, the output is dependent on the stability. Claim 88 is rejected in that the output includes a glucose numerical estimate on a display. Claim 89 is rejected in that the reference module receives data from a glucose test. Claims 91, 96, 97, 99, 102-104, 196, 197, and 199 are rejected for the reasons given above. Claims 178, 185, and 192 are rejected in that Shin has an alarm for glucose out of range situations.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 85, 87-89, 91, 92, 95-97, 99, 100, 102-104, 178-181, 185-188, and 192-199 are rejected under 35 U.S.C. 103(a) as being obvious over Say et al 6175752 in view of Shin et al 2002/0161288. Say teaches a continuous glucose sensing device that includes a sensor data receiving module 96, a reference data receiving module 99 that receives reference data from a reference glucose sensor, a module that calibrates the sensor data using the reference data, and a stability determination module that determines that sufficient time after implantation has passed to allow the sensor to be stable (see column 44, lines 2-5). It is unclear to the examiner whether Say uses matched data pairs to calibrate the data. However, Shin teaches that such a pair matching technique is a well known method for calibrating a glucose sensor. Hence, it would have been obvious to modify Say to use such a calibration technique, as it is merely the substitution of one known calibration technique for another. With respect to claim 87, Say teaches that it waits a predetermined time before calibrating the sensor. It seems to the examiner that prior to calibration, there is no output. Hence, the output is dependent on the stability. Claim 88 is rejected in that the output includes a glucose numerical estimate on a display. Claim 89 is rejected in that the reference module receives data from a glucose test (see column 43,

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lines 45-56). Claim 91 is rejected in that Say further teaches the method. Claim 92 is rejected in that while Say only teaches waiting a "specified period", the exact time for waiting would have been obvious to one skilled in the art. Claims 95-97 are rejected for the reasons given above. Claims 99, 100, and 102-104 are rejected for the reasons given above, noting that Say also teaches the system. Claim 178 is rejected in that Say has an alarm to warn the user of a current or upcoming hypoglycemic or hyperglycemic event (see column 45, lines 14-15). Claim 179 is rejected in that in order to the system predicts future values (see column 55, line 2). Claims 180-181 are rejected in that the control system controls an insulin pump. Since the output occurs only after stability is reached, then the pump also is controlled only when a stability level is reached. Claims 185-188, and 192-199 are rejected for the reasons given above.

Claims 90, 98, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shin et al in view of Causey III, et al 6558320. In figure 5, Causey shows a reference monitor integral with the processing device. Hence, it would have been obvious to modify Shin to use such an integral reference monitor, as it is merely the substitution of one known reference monitor for another.

Claims 90, 98, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al in view of Shin et al as applied to claims 85, 87-89, 91, 92 95-97, 99, 100, 102-104, 178-181, 185-188, and 192-199 above, and further in view of Causey III, et al 6558320. In figure 5, Causey shows a reference monitor integral with the processing device. Hence, it would have

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been obvious to modify the combination to use such an integral reference monitor, as it is merely the substitution of one known reference monitor for another.

Claims 93, 175-177, 182-184, and 189-191 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 93 defines over the art in that none of the art evaluates stability based on the matched data pair, as claimed.

Claims 175-176, 182-183, and 189-190 define over the art in that none of the art evaluates stability based on the sensitivity, as claimed.

Claims 177, 184, and 191 define over the art in that none of the art evaluates stability based on the oxygen, as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Berner et al 2005/0215872 teaches in paragraph [0128] waiting a period of time after implantation for the sensor to stabilize.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner  
Art Unit 3735

RLN  
July 11, 2008